

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT

FIFRA GLP INSPECTION REPORT

MicroChem Laboratory, Inc.
Euless, TX 76040

September 12 - 13, 2007 *mfd*

Daniel M. Myers

EPA, Office of Compliance, GLP Section
Denver, Colorado

REPORT OF A GLP COMPLIANCE INSPECTION CONDUCTED PURSUANT TO
THE FIFRA GLP REGULATIONS

LABORATORY: MicroChem Laboratory, Inc.
1107-C S. Airport Circle
Euless, TX 76040

INVESTIGATION ID: 20114954011

RESPONSIBLE OFFICIAL: Norman Miner Ph.D.
President
Phone: (817) 283-9100

DATE OF INSPECTION: September 12 - 13, 2011

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- A: GLP Compliance Review
- B: Study Audit Report: Ethanol, “Analysis of the Ethanol Concentration of Five Batches of Detox by Gas Chromatography” (Auditor: Daniel M. Myers)
- C: Study Audit Report: EcaFlo Electrolyzed Water, “Analysis of Five Lots of EcaFlo Electrolyzed Water for Free Available Chlorine, pH Value, and Hypochlorous Acid Concentration” (Auditor: Daniel M. Myers)
- D: Study Audit Report: ALPET D2, “A Confirmatory Study of the Sanitizing Activity of ALPET D2 Surface Sanitizing Wipes by the Methods of the EPA Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Toweletts” (Auditor: Daniel M. Myers)
- E: Study Audit Report: URTN, “A Study of the Bactericidal Activity of URTN by Methods of the AOAC Use Dilution Test with 5.0 Minutes Exposure at 20±1°C” (Auditor: Daniel M. Myers)

SUMMARY

A FIFRA GLP inspection was conducted at MicroChem Laboratory, Inc. in Euless, TX, on September 12 - 13, 2011. Four study audits were accomplished in addition to a GLP compliance review. The GLP compliance review was conducted using one study selected from the facility master schedule. Findings for the GLP compliance review and the study audits are summarized below:

These findings are associated with only one of the study audits. [Appendix B]

- Missing raw data
- Raw data not stored in archives
- No QA oversight of subcontracted analytical laboratory
- No maintenance records for Gas Chromatograph
- Study report did not contain the analytical facility's name and address
- Study report did not contain the signed and dated reports from the analytical facility

I. INTRODUCTION

A routine FIFRA Good Laboratory Practice (GLP) Standards compliance inspection was conducted at MicroChem Laboratory, Inc. (MicroChem) on September 12 - 13, 2011 at the request of the U.S. EPA Office of Compliance (OC). Dr. Norman Miner, President, was notified of the pending inspection via letter [Exhibit 1] from Francisca E. Liem, Director of OC's GLP Program. The letter identified the inspection team, the studies to be audited and the data and records to be made available.

The week prior to the inspection, Dr. Miner was contacted by the lead inspector, Daniel M. Myers, from OC's GLP Program via telephone to discuss the upcoming inspection logistics. Mr. Myers explained that he would conduct a neutral scheme inspection involving four study audits and a GLP compliance review.

The inspection team consisted only of Mr. Myers who conducted both the laboratory inspection and the study audits.

II. OPENING CONFERENCE

An opening conference was held beginning at approximately 2:50 p.m. on Monday, September 12, 2011. The inspection was led by Mr. Daniel M. Myers, Chemist, from EPA, GLP Program.

Official credentials were presented to Dr. Miner upon entry. A FIFRA Notice of Inspection [Exhibit 2] was presented to and signed by Dr. Miner. Mr. Myers informed facility employees that the inspection was routine in nature and that there were no previously suspected data or GLP problems involved.

MicroChem employees present at this conference consisted of Dr. Miner, Ms. Valerie Harris,

Laboratory Manager and Ms. Towanda Ebron, Microbiologist/Chemist. Facility officials gave a verbal summary of MicroChem's history including the scope of their operations and the extent of GLP involvement. Additional details for the conduct of the inspection were discussed and an inspection schedule was agreed upon.

III. HISTORY OF THE FACILITY

MicroChem laboratories, Inc. was started by Dr. Miner in 1988 and has remained in the same location in Euless, TX for the last 9 years. Throughout this time their focus has remained on the research, development, and testing for regulatory agencies of liquid chemical germicides. Approximately 25% of their work is regulated by the GLP standards for both the FDA and the EPA.

MicroChem consists of 4000 ft² of space in an office park. This space includes offices, laboratories, chemical and data storage areas. MicroChem currently employs 4 full time people.

Additional information can be found at www.microchemlab.net.

IV. EXIT CONFERENCE

The exit conference was held on Tuesday, September 12, 2011 by Mr. Myers to review findings and recommendations of the GLP standards inspection and data audits. MicroChem employees present at this conference were Dr. Miner, Ms. Harris, Ms. Ebron and Ms. Natalie Lukomski, Microbiologist/Chemist. An Inspection Observations form [Exhibit 3] was completed and copied for Dr. Miner, providing written indication of findings discussed in the closing conference. A FIFRA Receipt for Samples [Exhibit 4] was provided to Dr. Miner for all documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	Notification Letter (3 pages)
Exhibit 2	FIFRA <u>Notice of Inspection</u>
Exhibit 3	<u>Inspection Observations Form</u>
Exhibit 4	FIFRA <u>Receipt for Samples</u>

VI. SIGNATURE:

Inspector: Name: Daniel M. Myers
 Affiliation: Laboratory Data Integrity Branch


Daniel M. Myers

11/16/2011
Date

Exhibit 1

Letter of Notification (3 pages)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 2011

FAX AND POSTAL MAIL
CONFIRMATION OF RECEIPT REQUESTED

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Dr. Norman Miner
MicroChem Laboratory, Inc.
1107-C S. Airport Circle
Eulless, TX 76040

Dear Dr. Miner:

This is to inform you that the Environmental Protection Agency (EPA) will conduct a Good Laboratory Practice (GLP) inspection at your facility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The inspection will be conducted on September 12-15, 2011. The inspection will be led by Daniel Myers. The inspection team will review your facility's compliance status with the EPA FIFRA GLP regulations at 40 Code of Federal Regulations (CFR) Part 160 and will audit those aspects of the studies listed in Attachment I performed by MicroChem Laboratory, Inc.

In addition, the inspection team will choose one or more completed or ongoing studies from your Master Schedule for audit.

The purpose of study audits is to validate data in final reports which have been presented to the EPA in support of a registration or marketing petition under FIFRA.

The purpose of the compliance review is to determine that the GLP regulations of FIFRA are being observed in your testing facility's current procedures and practices for pertinent studies being conducted.

Please note that under the FIFRA GLP regulations at 40 CFR 160.15(b) EPA will not consider reliable for purposes of supporting a FIFRA application for a research or marketing permit any data developed by a testing facility that refuses to permit inspection.

To successfully conduct our inspection, we request that the following matters be addressed prior to our arrival at MicroChem Laboratory, Inc.


Please make available suitable space for the team. Please have available and in good order all original data needed to verify the final report of each study, along with full copies of the protocol (including protocol amendments) and all reports submitted by your facility to the study sponsors. All current personnel who were associated with these studies should be available for discussion with members of the team as necessary. The inspection team will need for review copies of all Standard Operating Procedures (SOP) documents in use at the time of study.

We will require very specific information at your facility regarding the analytical reference standards (reference substance). This includes, but is not necessarily limited to, the source and lot number, analysis for purity and identification, record of receipt and storage, usage data, test substance inventory logs and custodial procedures for each reference substance. Records and data should also be available to document the synthesis, radiochemical purity and specific activity of any radio-labeled test or reference substances used at your facility for the conduct of the studies being audited.

In addition, please obtain a statement from the sponsor indicating the origin of the test substance, namely, if it was sampled from a batch for contemporary commercial use or was synthesized or manufactured for the specific study for which the raw data are being audited. In either case, the statement should include chemistry data, i.e., all data to prove the identity and purity of the test substance, the identity of any and all impurities detected by sponsor or manufacturer, and data to prove storage stability of the test substance during the lifetime of the study.

If there are any questions arising from this notice please feel free to call me directly. Under ordinary conditions the dates selected for the inspection will not be changed. I may be reached during regular hours at (202) 564-2365.

Sincerely,



Francisca E. Liem, Director
Good Laboratory Practice Program

Enclosure

Attachment I

STUDY AUDITS

Test Substance	Study	Lab Project No.
001501 - Ethanol	Analysis of the Ethanol Concentration of Five Batches of Detox by Gas Chromatography (EPA ID 47320202)	070829-2
129054 - Hypochlorous Acid	Analysis of Five Lots of EcaFlo Electrolyzed Water for Free Available Chlorine, pH Value, and Hypochlorous Acid Concentration (EPA ID 47356602)	080213-1
047501 - Isopropanol	A Confirmatory Study of the Sanitizing Activity of ALPET D2 Surface	081002-2
069149 - Didecyl dimethyl ammonium chloride	Sanitizing Wipes by the Methods of the EPA Draft Interim Guidance for	
069165 - Octyl decyl dimethyl ammonium chloride	Non-Residual Sanitization of Hand ...	
069166 - Dioctyl dimethyl ammonium chloride	(EPA ID 47570601)	
001501 - Ethanol	A Study of the Bactericidal Activity of UPTH by Methods of the AOAC Use Dilution Test with 5.0 Minutes Exposure at 20+/- 1 Degrees Celcius (EPA ID 47677201)	080729-1

Exhibit 2

FIFRA Notice of Inspection



U.S. ENVIRONMENTAL PROTECTION AGENCY

GOOD LABORATORY PRACTICE NOTICE OF INSPECTION

ADDRESS (EPA Office)
Office of Compliance
Bldg. 25, Box 25227
Denver, CO 80225

DATE

9/12/11

HOUR

2:50 AM
PM

FIRM NAME

MicroChem Laboratory, Inc.

FIRM ADDRESS (NUMBER, STREET, CITY, STATE AND ZIP CODE)

1107-C S. Airport Circle
Euless, TX 76040

NAME OF OWNER OR AGENT IN CHARGE

NORMAN MINER

SIGNATURE OF OWNER OR AGENT IN CHARGE (SIGNATURE GRANTS CONSENT TO INSPECTION)

Norman Miner

SIGNATURE OF EPA EMPLOYEE

Daniel Myers

TITLE

TITLE

Chemist / Inspector

REASON FOR INSPECTION:



FOR THE PURPOSE OF PERFORMING AN INSPECTION PURSUANT TO THE GOOD LABORATORY PRACTICE STANDARDS SPECIFIED IN SECTION 40 CFR PART 160



FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, SECTIONS 8 and 12(a)(2)(B), AND IN SECTION 40 CFR PART 169.



VIOLATION SUSPECTED:

None.

Exhibit 3

Inspection Observations Form



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Box 25227, Bldg. 25
Denver Federal Center
Denver, CO 80225

DATE 9/13/2011

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO:

INVESTIGATION ID NUMBER

20114954011

FIRM NAME AND ADDRESS:

MicroChem Laboratory, Inc.
1107-C S. Airport Circle
Euless, TX 76040

FACILITY INSPECTED ADDRESS

Same.

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

For a FIFRA GLP Inspections and study Audits of Studies 080213-1,
070829-2, 081002-2 and 08729-1

The Following Findings are for Study 070829-2

- Missing original raw data. 40 CFR 169.2(k)
- ^{RM. 9/13/11} ~~Raw~~ Raw data not stored in archives 40 CFR 160.33(f)
- No QA oversight of GC Lab. 40 CFR 160.35(a)
- No maintenance records for GC. 40 CFR 160.63(c)
- Study report did not contain the analytical Facility's name and address 40 CFR 160.185(a)(1)
- Study report did not contain the signed and dated reports from the analytical Facility 40 CFR 160.185(a)(12)

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT

THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE

TITLE

PREPARED BY:

Daniel Myers

TITLE

Chemist / Inspector

Exhibit 4

FIFRA Receipt for Samples



U.S. ENVIRONMENTAL PROTECTION AGENCY

RECEIPT FOR SAMPLES

ADDRESS (EPA Regional Office)
Office of Compliance
Bldg. 25, Box 25227, DFC
Denver, CO 80225DATE
9/13/2011

NAME OF INDIVIDUAL

Norman Miner

TITLE

PRESIDENT

FIRM NAME

MicroChem Laboratory, Inc.

ADDRESS (Street, City, State and Zip Code)

1107-C S. Airport Circle
Euless, TX 76040

SAMPLE NUMBERS

SAMPLES COLLECTED (Describe fully. List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.)

The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged pursuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form.

- 1) Brochure, organization chart, Floor plan (3 pages)
- 2) Protocol for study 080213-1 (7 pages)
- 3) Protocol for study 070829-2 (5 pages)
- 4) Protocol for study 081002-2 (10 pages)
- 5) Protocol for study 080729-1 (10 pages)
- 6) Protocol for recently completed study 110711-1 (9 pages)
- 7) Amended Final Study Report for study 070829-2 (12 pages)
- 8) EPA Correspondence for study 070829-2 (2 pages)
- 9) QAU Inspection Record for study 070829-2 (1 page)

ACKNOWLEDGMENT OF PRODUCER/REGISTRANT

The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.

SIGNATURE (Owner, Operator, or Agent)

Norman Miner

TITLE (Owner, Operator or Agent)

PRESIDENT

☐ DUPLICATE SAMPLES
REQUESTED AND PROVIDED☐ DUPLICATE SAMPLES
NOT REQUESTED

SAMPLES WERE

☐ PURCHASED☐ BORROWED

AMOUNT PAID FOR SAMPLES

\$

☐ CASH☐ VOUCHER☐ TO BE BILLED

NAME OF COLLECTOR (Print or type)

Daniel Myers

TITLE OF COLLECTOR

Chemist / Inspector

SIGNATURE OF COLLECTOR

Daniel Myers